Delcath Systems Reports First Quarter 2024 Results and Business Highlights

May 14, 2024

Conference Call Today at 8:30 am Eastern Time

QUEENSBURY, N.Y., May 14, 2024 /PRNewswire/ -- Delcath Systems, Inc. (Nasdaq: DCTH) ("Delcath" or the "Company"), an interventional oncology company focused on the treatment of primary and metastatic cancers of the liver, today reported financial results and business highlights for the first quarter ended March 31, 2024.

Recent Business Highlights
During and since the first quarter, Delcath:

- Recognized over $2.0 million of revenue from sales of HEPZATO KIT (melphalan/Hepatic Delivery System) and $1.1 million in CHEMOSAT sales through March 31, 2024;
- Updated U.S. center activation guidance from 15 active centers to a total of 20 active centers by the end of 2024;
- Activated four treating centers during the first quarter with an additional two centers in April. A further five centers are accepting patient referrals in anticipation of activation;
- Raised $7.0 million in a private placement transaction with certain accredited investors comprised of existing investors, Delcath senior executives, and members of its Board of Directors;
- Appointed Martha S. Rook, Ph.D, an experienced industry leader with more than 25 years of academic and industry experience, as Chief Operating Officer;
- Received a permanent, product-specific J-code (J9248) and transitional pass-through payment status for HEPZATO KIT from the Centers for Medicare & Medicaid Services (CMS) which became effective on April 1, 2024;
- Executed an amendment with Synerx Pharma, LLC and Mylan Teoranta for Delcath's supply of melphalan hydrochloride which extends the term of the original agreement to December 31, 2028; and
- Announced the publication of results from the pivotal Phase 3 FOCUS study of HEPZATO KIT in patients with unresectable metastatic Uveal Melanoma on May 4, 2024, in the journal Annals of Surgical Oncology.

"We continue to make steady progress in the training and activation of new treatment centers which is a testament to both the emerging role of HEPZATO in the treatment of patients with metastatic uveal melanoma and the capability and dedication of our field force," said Gerard Michel, Delcath's Chief Executive Officer. "We are committed to expanding the availability of HEPZATO to patients in need and I am confident that we will reach our goal of 20 treating centers by the end of 2024."

First Quarter 2024 Results
Cash, cash equivalents and investment totaled $27.2 million as of March 31, 2024, which includes a $7.0 million private placement financing which closed on March 19, 2024.

Total revenue for the quarter ended March 31, 2024 was $3.1 million compared to $0.6 million for the same period in the prior year from our sales of HEPZATO in the U.S. and CHEMOSAT in Europe.

Research and development expenses for the quarter ended March 31, 2024, were $3.7 million compared to $4.6 million for the same period in the prior year. The change in research and development expenses is primarily due to a decrease in clinical trial activities and expenses related to the FDA inspection offset by an increase in personnel related expenses.

Selling, general and administrative expenses for the quarter ended March 31, 2024, were $8.8 million compared to $4.2 million for the same period in the prior year. The increase primarily relates to commercial launch activities including marketing-related expenses and additional personnel in the commercial team.

Conference Call Information
To participate in this event, dial in approximately 5 to 10 minutes before the beginning of the call.

Event Date:	Tuesday, May 14, 2024
Time:	8:30 AM Eastern Time

Participant Numbers	
Toll Free:	1-833-630-1960
International:	1-412-317-1841
Webcast:	https://app.webinar.net/PKDyZ5PV2aB

Conference Replay	
US Toll Free:	1-877-344-7529
International Toll:	1-412-317-0088
Replay Access Code:	9490444
End Date:	May 21, 2024

About Delcath Systems, Inc., HEPZATO KIT and CHEMOSAT
Delcath Systems, Inc. is an interventional oncology company focused on the treatment of primary and metastatic liver cancers. The company's proprietary products, HEPZATO KIT™ (Hepzato (melphalan) for Injection/Hepatic Delivery System) and CHEMOSAT® Hepatic Delivery System for Melphalan percutaneous hepatic perfusion (PHP), are designed to administer high-dose chemotherapy to the liver while controlling systemic exposure and associated side effects during a PHP procedure.

In the United States, HEPZATO KIT is considered a combination drug and device product and is regulated and approved for sale as a drug by the FDA. HEPZATO KIT is comprised of the chemotherapeutic drug melphalan and Delcath's proprietary Hepatic Delivery System (HDS). The HDS is used to surgically isolate the liver while simultaneously filtrating hepatic venous blood during melphalan infusion and washout. The use of the HDS results in loco-regional delivery of a relatively high melphalan dose, which can potentially induce a clinically meaningful tumor response with minimal hepatotoxicity and reduce systemic exposure. HEPZATO KIT is approved in the United States as a liver-directed treatment for adult patients with metastatic uveal melanoma (mUM) with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation. Please see the full Prescribing Information, including BOXED WARNING for the HEPZATO KIT.

In Europe, the device-only configuration of the HDS is regulated as a Class III medical device and is approved for sale under the trade name CHEMOSAT Hepatic Delivery System for Melphalan, or CHEMOSAT, where it has been used in the conduct of percutaneous hepatic perfusion procedures at major medical centers to treat a wide range of cancers of the liver.

Safe Harbor / Forward-Looking Statements
The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by the Company or on its behalf. This press release contains forward-looking statements, which are subject to certain risks and uncertainties, that can cause actual results to differ materially from those described. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Factors that may cause such differences include, but are not limited to, uncertainties relating to: the Company's commercialization plans and its ability to successfully commercialize the HEPZATO KIT; the Company's successful management of the HEPZATO KIT supply chain, including securing adequate supply of critical components necessary to manufacture and assemble the HEPZATO KIT; successful FDA inspections of the facilities of the Company and those of its third-party suppliers/manufacturers; the Company's successful implementation and management of the HEPZATO KIT Risk Evaluation and Mitigation Strategy; the potential benefits of the HEPZATO KIT as a treatment for patients with primary and metastatic disease in the liver; the Company's ability to obtain reimbursement for the HEPZATO KIT; and the Company's ability to successfully enter into any necessary purchase and sale agreements with users of the HEPZATO KIT. For additional information about these factors, and others that may impact the Company, please see the Company's filings with the Securities and Exchange Commission, including those on Forms 10-K, 10-Q, and 8-K. However, new risk factors and uncertainties may emerge from time to time, and it is not possible to predict all risk factors and uncertainties. Accordingly, you should not place undue reliance on these forward-looking statements, which speak only as of the date they are made. We undertake no obligation to publicly update or revise these forward-looking

statements to reflect events or circumstances after the date they are made.

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DELCATH SYSTEMS, INC.
Condensed Consolidated Balance Sheets
(Unaudited)
(*in thousands, except share and per share data)*

	March 31, 2024	December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	$ 11,760	$ 12,646
Restricted cash	50	50
Short-term investments	15,360	19,808
Accounts receivable, net	1,564	241
Inventory	3,634	3,322
Prepaid expenses and other current assets	1,278	1,091
Total current assets	33,646	37,158
Property, plant and equipment, net	1,336	1,352
Right-of-use assets	1,117	103
Total assets	$ 36,099	$ 38,613
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 1,487	$ 1,012
Accrued expenses	4,395	5,249
Lease liabilities, current	102	37
Loan payable	2,408	5,239
Convertible notes payable	4,949	4,911
Total current liabilities	13,341	16,448
Warrant liability	6,160	5,548
Lease Liabilities, non-current	1,016	—
Other liabilities, non-current	962	840
Total liabilities	21,479	22,836
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.01 par value; 10,000,000 shares authorized; 16,809 and 24,819 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.01 par value; 80,000,000 shares authorized; 25,439,319 shares and 22,761,554 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	254	228
Additional paid-in capital	530,482	520,576
Accumulated deficit	(516,273)	(505,162)
Accumulated other comprehensive loss	157	135
Total stockholders' equity	14,620	15,777
Total liabilities and stockholders' equity	$ 36,099	$ 38,613

DELCATH SYSTEMS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share data)

	Three months ended March 31,	
	2024	2023
Product revenue	$ 3,139	$ 597
Other revenue	—	—
Total revenues	3,139	597
Cost of goods sold	(903)	(181)
Gross profit	2,236	416
Operating expenses:		
Research and development expenses	3,700	4,576
Selling, general and administrative expenses	8,814	4,165
Total operating expenses	12,514	8,741
Operating loss	(10,278)	(8,325)
Change in fair value of warrant liability	(612)	—
Interest expense, net	(199)	(688)
Other (expense) income	(22)	13
Net loss	(11,111)	(9,000)
Other comprehensive (loss) income:		
Unrealized gain on investments	8	—
Foreign currency translation adjustments	14	19
Total comprehensive loss	$ (11,089)	$ (8,981)
Common share data:		
Basic and diluted loss per common share	$ (0.45)	$ (0.77)
Weighted average number of basic and diluted shares outstanding	24,887,180	11,622,384

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